



DEPARTMENT OF HEALTH & HUMAN SERVICES

95119d  
Public Health Service

Food and Drug Administration  
Detroit District  
300 River Place  
Suite 5900  
Detroit, MI 48207  
Telephone: 313-393-8100  
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CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

December 15, 2004

WARNING LETTER  
2005-DT-06

Mr. Gregory Rogers  
President  
Precision Piece Parts, Inc.  
712 S. Logan Street  
Mishawaka, IN 46544-4832

Dear Mr. Rogers:

An inspection of your facility was conducted from August 30 through September 21, 2004. The purpose of the inspection was to evaluate the adequacy of your activities related to the manufacturing of finished medical devices. The ilio-sacral bone screws, as well as other medical products manufactured by your firm for your customer, [REDACTED] are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). This inspection revealed that these devices are adulterated within the meaning of Section 501 of the Act, as explained further below.

The above-referenced inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacture, packing, storage, or installation are not in conformance with the current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulation (QS regulation), as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. You failed to comply with the Quality System Management Responsibility requirements of 21 CFR 820.20(a) – (e). [See, for example, FDA-483 observations 1, 2, 4, 5, 8, 13, 14 and 15].

2. You failed to establish effective procedures for or to conduct quality audits, as required by 21 CFR 820.22. [See, for example, FDA-483 observation 7.].
3. You failed to establish and follow effective document approval procedures, as required by 21 CFR 820.40(a). [See, for example, FDA-483 observations 20 (examples 1a & 1b) and 21.].
4. You failed to establish and follow effective procedures for the evaluation of suppliers, contractors, and consultants, as required by 21 CFR 820.50(a). [See, for example, FDA-483 observation 6 (examples 1 and 2).].
5. You failed to establish and follow effective procedures for identifying, with a control number, each unit, lot, or batch of finished devices intended for surgical implant into the body, as required by the traceability regulations of 21 CFR 820.65. [See, for example, FDA-483 observation 29.].
6. You failed to establish production and process control procedures, such as defining the Device Master Records (DMR), the Device History Records (DHR), and procedures for monitoring production and quality operations, as required by 21 CFR 820.70(a). [See, for example, FDA-483 observation 3.].
7. You failed to establish procedures for, or to perform verification or validation of changes to specifications, methods, or processes, as required by 21 CFR 820.70(b). [See, for example, FDA-483 observation 17.].
8. You failed to validate the original and subsequent changes to computer software used to control automated production and quality system operations, as required by 21 CFR 820.70(i). [See, for example, FDA-483 observations 18 and 19.].
9. You failed to verify or validate production processes, such as the [REDACTED] and [REDACTED] operations, and various in-process production operations performed by 3<sup>rd</sup> party contractors, as required by 21 CFR 820.75(a). [See, for example, FDA-483 observation 16.].
10. You failed to establish procedures for or to conduct a review of the Device History Records and associated quality system records prior to release of the devices for distribution, as required by the final acceptance activities section of 21 CFR 820.80(d). [See, for example, FDA-483 observation 25.].
11. You failed to establish complete and effective procedures for addressing non-conforming product and rework operations as required by 21 CFR 820.90(a) and (b)(2). [See, for example, FDA-483 observations 9, 10 and 11.].

12. You failed to establish, document, and follow effective procedures for addressing Corrective and Preventive Action (CAPA) operations, as required by 21 CFR 820.100(a) and (b). [See, for example, FDA-483 observation 12.].
13. You failed to establish and follow effective procedures to include your "internal" lot numbers in the finished product distribution records, as required by 21 CFR 820.160(b)(4). [See, for example, FDA-483 observation 28.].
14. You failed to maintain complete Device Master Records (DMR) that include all the elements required by 21 CFR 820.181. [See, for example, FDA-483 observations 22 and 23.].
15. You failed to establish and maintain procedures to ensure that Device History Records (DHRs) demonstrate that devices are manufactured according to the Device Master Records, as required by 21 CFR 820.184. [See, for example, FDA-483 observations 24 and 30.].

This letter is not intended to be an all inclusive review of your firm's compliance status. It is your responsibility to assure adherence to each requirement of the regulations. Other Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Additionally, pending 510(k) or PMA applications and export approval requests may not be approved until the violations are corrected.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products, the assessment of civil money penalties, and for injunction against the manufacturer and/or distributor of illegal products.

We acknowledge receipt of the September 30, 2004 letter of Mr. Larry Cabanaw, General Manager written in response to the FDA-483. His letter presents an explanation for the failure to be in compliance with the requirements of the Quality System Regulation under 21 CFR 820, and a commitment to bring your quality system into compliance. However, his letter does not present the detailed responses necessary for FDA to evaluate whether the firm is addressing its quality system compliance problems.

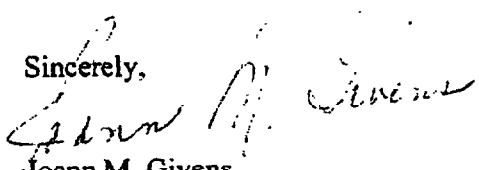
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Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, as to the specific steps you have taken to correct these violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If correction actions cannot be completed within 15 working days, please state the reason for the delay and the time frame within which the corrections will be implemented.

Your reply should be directed to Melvin O. Robinson, Compliance Officer, at the above address.

Sincerely,

  
Joann M. Givens  
District Director  
Detroit District

Encl: FDA-483

Cc via certified mail:

Mr. Larry Cabanaw  
General Manager  
Precision Piece Parts, Inc.  
712 S. Logan St.  
Mishawaka, IN 46544

[REDACTED]